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10/826,654

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EXAMINER

LU, FRANK WEI MIN

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

12/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/826,654 | Applicant(s) NADEAU ET AL. | |
| | Examiner FRANK W. LU | Art Unit 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2008 and 29 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74, 76 and 78-114 is/are pending in the application.
- 4a) Of the above claim(s) 9, 16-19, 31-73 and 79-114 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-15, 20-30, 74, 76 and 78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/9/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on June 16, 2008 and supplemental amendments filed on September 29, 2008 has been entered. The claims pending in this application are claims 1-74, 76, and 78-114 wherein claims 9, 16-19, 31-73, and 79-114 have been withdrawn due to the restriction requirement and the election of species mailed on September 28, 2006. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of applicant's amendments filed on June 16, 2008 and September 29, 2008. Therefore, claims 1-8, 10-15, 20-30, 74, 76, and 78 will be examined.

Election/Restrictions

2. This application contains claims 31-73 and 79-114 drawn to an invention nonelected in the reply filed on February 2, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Drawings

3. Figure 13 submitted on September 29, 2008 has been accepted by the office.

Oath/Declaration and Abstract

4. The oath/declaration and abstract submitted on June 16, 2008 have been accepted by the office.

Specification

5. The disclosure is objected to because of the following informality: there are several nucleotide sequences having more than 10 nucleotides in Figure 13. However, there is no SEQ ID NO for Probe-P1 in Figure 13 or BRIEF DESCRIPTION OF THE DRAWINGS in the specification does not provide SEQ ID NO for Probe-P1.

Appropriate correction is required.

Claim Objections

6. Claim 5 is objected to because of the following informality: “the hybridization blocker” should be “the hybridization blocker oligonucleotide”.

7. Claim 8 is objected to because of the following informality: “the length of the entire first oligonucleotide” should be “the length of the first oligonucleotide”.

8. Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim because the hybridization blocker oligonucleotide have hybridized with the first portion of the first oligonucleotide in step (ii) of claim 1. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

9. Claim 74 is objected to because of the following informality: “a 3’ terminus of the second oligonucleotide” in step (ii) should be “3’ terminus of the second oligonucleotide”.

10. Claim 78 is objected to because of the following informality: “a 5’ terminus of the third oligonucleotide” in step (ii) should be “5’ terminus of the third oligonucleotide”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. New Matter

Claims 76 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation “adding a splint oligonucleotide wherein a first portion of the splint oligonucleotide hybridizes with the first portion of the first oligonucleotide and a second portion of the splint oligonucleotide hybridizes with the first portion of the second oligonucleotide” is added to the newly amended dependent claim 76. Although the specification describes to add a splint oligonucleotide wherein a first portion of the splint oligonucleotide hybridizes with the first portion of the first oligonucleotide and a second portion of the splint oligonucleotide hybridizes with the first portion of the second oligonucleotide (e.g., see Figure 2A), since claim 76 is dependent on claim 74, claim 76 is read as further comprising adding a splint oligonucleotide wherein a first portion of the splint oligonucleotide hybridizes with the first portion of the first oligonucleotide and a second portion of the splint oligonucleotide hybridizes with the first portion of the second oligonucleotide and wherein the first portion of the first oligonucleotide hybridizes to the first portion of the second oligonucleotide, the specification fails to define or provide any disclosure to support adding a splint oligonucleotide wherein a first

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portion of the splint oligonucleotide hybridizes with the first portion of the first oligonucleotide and a second portion of the splint oligonucleotide hybridizes with the first portion of the second oligonucleotide and wherein the first portion of the first oligonucleotide hybridizes to the first portion of the second oligonucleotide as recited in claim 76. Furthermore, in applicant's remarks filed on September 29, 2008, applicant does not indicate which part in the specification supports such claim limitation.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-8, 10-15, 20-30, 74, 76, and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. Claim 1 is rejected as vague and indefinite in view of step (iii). Since, in step (i), a second oligonucleotide is capable of forming a hybrid with the first portion of the first oligonucleotide and the hybridization blocker oligonucleotide is capable of forming a hybrid with the first portion of the first oligonucleotide while, in step (ii), a complex comprising the analyte, the first

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proximity member, and the second proximity member, and the hybridization blocker oligonucleotide is formed, in view of steps (i) and (ii), there is a hybrid formed by the second oligonucleotide and the first portion of the first oligonucleotide and another hybrid formed by the hybridization blocker oligonucleotide and the first portion of the first oligonucleotide in the complex comprising the analyte, the first proximity member, and the second proximity member, and the hybridization blocker oligonucleotide. Since the claim does not require that there is no hybrid formed by the hybridization blocker oligonucleotide and the first portion of the first oligonucleotide and does not require that the binding affinity of the hybridization blocker oligonucleotide to the first portion of the first oligonucleotide is lower than the binding affinity of the second oligonucleotide to the first portion of the first oligonucleotide, it is unclear why a hybrid formed by the portion of the second oligonucleotide and the first portion of the first oligonucleotide can be produced by displacing the hybridization blocker oligonucleotide from the hybrid formed by the hybridization blocker oligonucleotide and the first portion of the first oligonucleotide as recited in step (iii). Please clarify.

16. Claim 1 is rejected as vague and indefinite in view of steps (iii) and (iv). Since step (iii) does not require that 5' portion of the first or second oligonucleotide is single stranded and is not complementary to the first or second oligonucleotide, it is unclear why an amplicon can be produced by extending the 3' terminus of the first or second oligonucleotide. Please clarify.

17. Claim 1 is rejected as vague and indefinite in view of step (vi) because the phrase "wherein detection of the amplification product allows detection of the analyte" does not make sense. Does this phrase mean that the detection of the amplification product indicates detection of the analyte? Please clarify.

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18. Claim 6 is rejected as vague and indefinite because the claim does not make sense. Does this phrase mean that the hybridization blocker oligonucleotide contains bases that are complementary with all of the bases of the first portion of the first oligonucleotide? Please clarify.

19. Claim 13 is rejected as vague and indefinite because it is unclear whether a double-stranded portion of the hybridization blocker oligonucleotide is capable of forming a hybrid with the first portion of the first oligonucleotide. Please clarify.

20. Claim 20 is rejected as vague and indefinite. Since claim 20 requires adding a second hybridization blocker oligonucleotide that is capable of hybridizing to the portion of the second oligonucleotide while claim 1 requires that the portion of the second oligonucleotide is capable of forming a hybrid with the first portion of the first oligonucleotide, the hybridization blocker oligonucleotide is capable of forming a hybrid with the first portion of the first oligonucleotide, and a hybrid formed by the portion of the second oligonucleotide and the first portion of the first oligonucleotide can be produced by displacing the hybridization blocker oligonucleotide from the hybrid formed by the hybridization blocker oligonucleotide and the first portion of the first oligonucleotide, in view of claim 20, the addition of a second hybridization blocker oligonucleotide that is capable of hybridizing to the portion of the second oligonucleotide prevents to produce a hybrid formed by the portion of the second oligonucleotide and the first portion of the first oligonucleotide. Thus, claims 1 and 20 do not correspond each other. Please clarify.

21. Claim 22 is rejected as vague and indefinite. Since claim 1 does not require hybridizing the first oligonucleotide to the second oligonucleotide before adding the hybridization blocker

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oligonucleotide, it is unclear why the hybridization blocker can reduce formation of the amplicon by hybridization of the first and second oligonucleotides prior to forming a complex by a factor of at least 100-fold. Furthermore, it is unclear a complex in the claim is identical to the complex in step (ii) of claim 1 or not. In addition, it is unclear why the hybridization blocker can reduce formation of the amplicon by a factor of at least 100-fold. Please clarify.

22. Claim 23 is rejected as vague and indefinite because it is unclear why the hybridization blocker can reduce formation of the amplicon by a factor of at least 1000-fold. Please clarify.

23. Claim 28 is rejected as vague and indefinite. Since claim 1 requires that the first or second analyte-specific binding entity is a protein while claim 28 requires that the first or second analyte-specific binding entity is a protein complex which is a complex formed by a protein and other compound, claims 1 and 28 do not correspond each other. Please clarify.

24. Claim 74 is rejected as vague and indefinite in view of step (iii). Since either the first oligonucleotide or the second oligonucleotide contains 3' terminus, it is unclear that the 3' terminus is from a 3' terminus of the second oligonucleotide or not. Please clarify.

25. Claim 74 or 78 is rejected as vague and indefinite in view of step (v) because the phrase "wherein detection of the amplification product allows detection of the analyte" does not make sense. Does this phrase mean that the detection of the amplification product indicates detection of the analyte? Please clarify.

Conclusion

26. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

27. No claim is allowed.

28. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746.

The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

/Frank W Lu /, Primary Examiner, Art Unit 1634
December 18, 2008